



Artivion Announces Presentation of Late-Breaking Data from AMDS PERSEVERE and AMDS PROTECT Trials at the 39th European Association for Cardio-Thoracic Surgery (EACTS) Annual Meeting

October 13, 2025

30-day Data from the AMDS PERSEVERE Trial Demonstrates Visceral Malperfusion Resolution in 83%, and Renal Malperfusion Resolution in 74% of Affected Subjects Post-AMDS Implantation

Real-World Data from the AMDS PROTECT Trial Validate Statistically Significant Positive Outcomes Demonstrated by the PERSEVERE and DARTS trials

ATLANTA, Oct. 13, 2025 /PRNewswire/ -- **Artivion, Inc. (NYSE: AORT)**, a leading cardiac and vascular surgery company focused on aortic disease, today announced data from its AMDS PERSEVERE and PROTECT trials were presented in Late-Breaking Science presentations at the 39th European Association for Cardio-Thoracic Surgery (EACTS) Annual Meeting in Copenhagen, Denmark.

The AMDS PERSEVERE trial presentation highlighted positive 30-day data focused on a subset of patients with visceral and renal malperfusion. The results demonstrate resolution of visceral malperfusion in 83% and renal malperfusion in 74% of affected subjects following AMDS implantation. Real-world results from the AMDS PROTECT trial further confirm the statistically significant positive clinical outcomes demonstrated in the PERSEVERE IDE study.

Dr. Michael Moon, Clinical Associate Professor of Surgery at University of Alberta, Canada, steering committee member of the PERSEVERE trial and co-principal investigator of the PROTECT trial, said "The latest data from these two ongoing long-term studies of AMDS continue to highlight how this critical technology is improving outcomes for some of our sickest patients."

"We were thrilled to command such a strong presence at EACTS with data from our AMDS clinical trials featured in two late-breaking science sessions," said Pat Mackin, Chairman, President, and Chief Executive Officer of Artivion. "These results further validate the strength of our best-in-class portfolio and reinforce our commitment to advancing innovation in the treatment of aortic disease."

Late-Breaking Data from AMDS PERSEVERE Trial:

The abstract titled *Effectiveness of AMDS Hybrid Prosthesis in Resolving Visceral and Renal Malperfusion in Acute DeBakey Type I Dissection – Results from the PERSEVERE Study* focuses on the assessment of downstream benefits of AMDS, specifically visceral and renal malperfusion resolution at 30-days following AMDS implantation in the 40 study participants presenting with clinical malperfusion of those organs.

- 83% of patients with pre-operative visceral malperfusion did not develop any significant gastrointestinal events including bowel ischemia, ileus, bleeding, abdominal pain, the need for laparotomy, or artery stenting.
- 74% of patients with pre-operative renal malperfusion did not develop renal failure requiring dialysis or the need for artery stenting, and all had radiographic resolution.

Importantly, the analysis evaluated patients with and without pre-operative symptomatic malperfusion and found no meaningful difference in clinical outcomes between the two groups, underscoring the consistent performance of AMDS, even in higher-risk patients.

Late-Breaking Data from AMDS PROTECT Trial:

The abstract titled *The AMDS Hybrid Prosthesis for the Treatment of Acute DeBakey Type I Dissection: 3-6 Month Results of European and Canadian Multicenter PROTECT Registry* reports real-world usage of AMDS across 141 patients. The real-world results from this registry demonstrate excellent outcomes consistent with those of the PERSEVERE and DARTS studies:

	PROTECT (%)	STS Adult Cardiac Surgery Database ¹ (%)
Disabling stroke	12.6	11.2 - 15.6
Renal failure requiring dialysis	4.2	12.4 - 25.1
Unanticipated reoperation	1.4	16.3 - 25.4

There were no occurrences of paralysis/paraparesis, aortic rupture, or myocardial infarction and 95.3 to 100% of patients experienced positive remodeling with true lumen diameter increasing or stable in zones 1, 2, and 3.

About the AMDS PERSEVERE Clinical Trial

The PERSEVERE trial is a prospective, multicenter, non-randomized clinical trial to determine if patients with acute DeBakey Type I aortic dissection can be treated safely and effectively using the AMDS Hybrid Prosthesis. The trial is designed to support the Company's forthcoming application to the U.S. Food and Drug Administration (FDA) for premarket approval of the AMDS. The trial consists of 93 participants in the U.S., who have experienced an acute DeBakey Type I aortic dissection complicated by malperfusion. Each participant will be followed for up to 5 years. 30-day trial data met combined safety and primary efficacy endpoints, demonstrating significant reduction of major adverse events (MAEs), including all-cause mortality, stroke, renal failure requiring dialysis, and myocardial infarction, and distal anastomotic new entry (DANE) tears following AMDS implantation. The secondary endpoint relates to remodeling of the aorta.

About the AMDS PROTECT Trial

The AMDS PROTECT trial is a real-world, observational, prospective and retrospective, non-randomized, non-interventional study to investigate the performance and clinical benefits of AMDS to treat patients with acute DeBakey type I dissections with or without clinically relevant preoperative malperfusion and/or intramural hematomas. The registry has enrolled 302 participants in Europe and Canada. The current presentation reports on 141 of 300 participants who have reached the 3- to 6-month follow-up.

About the AMDS Hybrid Prosthesis and Acute DeBakey Type I Aortic Dissections

The AMDS is the world's first aortic arch remodeling device for use in the treatment of acute DeBakey Type I aortic dissections. It is used as a complement to, and in conjunction with, hemiarch replacement without adding technical complexity. The design of the AMDS allows for rapid deployment of the graft in the aortic arch during a standard replacement of the ascending aorta, with deployment adding minimal time to the procedure. The deployment of the AMDS preserves the native arch, allowing for minimally invasive re-interventions if needed, rather than an invasive arch repair. AMDS is available in the United States under an HDE and in select markets around the world including Europe, Canada and certain countries in Asia. The PERSEVERE clinical trial underpinning the AMDS PMA met its primary endpoints and demonstrated a 72% reduction in all-cause mortality and a 54% reduction in primary major adverse events (MAEs), with zero occurrence of distal anastomotic new entry, or DANE, when compared to the current standard of care hemiarch procedure at 30-days following AMDS implantation. In the clinical trial DARTS supporting the CE Mark and Health Canada approvals, the AMDS was shown to reduce complications and reoperations in comparison to published rates with the standard of care, thereby improving the care of patients and offering potential cost savings for the health care system.

Globally, approximately 48,000 patients suffer annually from acute DeBakey Type I aortic dissections, representing an estimated \$150 million market opportunity in the United States and \$540 million market opportunity globally, pending regulatory approvals. Aortic dissection occurs when the innermost layer of the aorta tears and blood surges through the tear separating the layers of the aorta. In acute DeBakey Type I aortic dissections, the dissection flap originates in the ascending aorta and continues down into the descending thoracic aorta. Left untreated, aortic dissections lead to death in about half of patients within the first 3 days. The current standard of care for repairing acute DeBakey Type I aortic dissections with a primary entry tear in the ascending aorta is a hemiarch repair which involves open chest surgery during which the ascending thoracic aorta is replaced. Though this typically addresses the most critical and pressing issues resulting from acute DeBakey Type I dissections, it is often not enough. Hemiarch repair alone does not address downstream true lumen expansion or treat the false lumen beyond the ascending aorta, which could lead to costly and fatal complications such as malperfusion with subsequent end-organ ischemia resulting from a lack of blood-flow and continued pulsatile blood flow in the false lumen leading to aneurysmal growth of the aorta.

About Artivion, Inc.

Headquartered in suburban Atlanta, Georgia, Artivion, Inc. is a medical device company focused on developing simple, elegant solutions that address cardiac and vascular surgeons' most difficult challenges in treating patients with aortic diseases. Artivion's four major groups of products include: aortic stent grafts, surgical sealants, On-X mechanical heart valves, and implantable cardiac and vascular human tissues. Artivion markets and sells products in more than 100 countries worldwide. For additional information about Artivion, visit our website, www.Artivion.com.

Reference:

1. Goel NJ, K. J., Patrick WL, Zhao Y, Bavaria JE, Ouzounian M, Estrera AL, Takayama H, Chen EP, Reece TB, Hughes GC, Roselli EE, Kim KM, Patel HJ, Bowdish ME, Sperling JS, Leshnowar BG, Preventza O, Brinkman WT, Desai ND. (2025). Malperfusion in Patients with Acute Type A Aortic Dissection: A Nationwide Analysis. *Annals of Thoracic Surgery*. Volume 119, Issue 5, 980 – 989.

Contacts:

Artivion

Lance A. Berry
Executive Vice President, Chief
Operating Officer & Chief Financial Officer
Phone: 770-419-3355

Gilmartin Group LLC

Brian Johnston
Laine Morgan
Phone: 332-895-3222
investors@artivion.com

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